UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/530,363	05/01/00	GABERT J	1721-21

HM12/0110

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EXAMINER	
SPIEGLER, A	
ART UNIT	**PAPER NUMBER**
1656	6

DATE MAILED: 01/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/530,363	GABERT, JEAN	
	Examiner	Art Unit	
	Alexander H. Spiegler	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Notice to Comply* .

DETAILED ACTION

Sequence Notes

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specification

2. The disclosure is objected to because of the following informalities:

A) Page 3a, ln. 20, recites "jonction", which should be amended to recite "junction".

B) Page 6, ln. 1, recites "desoxynucleotide", which could be amended to recite "deoxynucleotide".

C) Page 7, ln. 10 and ln. 18, recites "immunobolized", which should be amended to recite "immobilized".

D) Page 9, ln. 3, pg. 16, ln. 3, pg. 21, ln. 21, and claim 8 recites "sens", which could be amended to recite "sense".

E) Page 13, ln. 19-20, refers to a single figure, but no figure is specified.

F) Claim 5, recites "denaturated", which can be amended to recite "denatured".

G) Claim 7, recites "the DNA or RNA of the gene_, the fusion...", which could be amended to recite "the DNA or RNA of the gene, the fusion...".

H) Claim 8, recites "a specific probes", which could be amended to recite "a specific probe".

I) Claims 11-12, recite "according to to", which could be amended to recite "according to".

J) The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
1. Field of the Invention.
2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

K) This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-15 are indefinite because they appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, the claims could be amended to recite, "A method of diagnosing a pathology associated with gene rearrangement, wherein a patient's DNA or cDNA is subjected to a step of anchored PCR, in vitro, comprising;".

B) Claims 1-15 are indefinite over the recitation of "associated with gene rearrangement" because it is not clear as to what is meant by this recitation. For example, it is not clear as to whether this refers to a translocation, a deletion, or some other rearrangement.

C) Claims 1-15 are indefinite and vague because the claims are written in the passive tense. Method claims should recite positive, active process steps (see Ex parte Erlich 3 USPQ 2d 1011). For example, this rejection may be overcome by amending the claims to recite " (a) performing one or more steps of asymmetrical PCR, wherein a single pair of primers consisting of ...; (b) obtaining a PCR product; (c) detecting...; (d) diagnosing...".

D) Claims 1-15 are indefinite because the claims do not recite a final process step which clearly relates back to the preamble. The preamble states that the method is for a method for diagnosing pathologies associated with gene rearrangement, but the final process step is detecting PCR products. Therefore, it is unclear as to whether the claim is intended to be limited to a method of diagnosing pathologies associated with gene rearrangement or a method of detecting PCR products. The claims could be amended to recite, "detecting PCR products..., wherein the detection of a PCR product is indicative of a pathology associated with gene rearrangement".

E) Claims 1-15 are indefinite over the recitation of "carried out in a non specific manner" because it is not as clear as to what is encompassed in "a non specific manner" or how one carries out a "non specific manner".

F) Claims 1-15 are indefinite over the recitation of "of gene rearrangements" because it is not clear as to whether the asymmetrical PCR causes the gene rearrangements or whether the non

specific manner of the asymmetrical PCR causes the gene rearrangements, or gene rearrangements is one of the steps of asymmetrical PCR, etc.

G) Claims 1-15 are indefinite over the recitation of "consisting in one primer" because it is not clear as to how a single pair of primers can consist "in" one primer. The claims could be amended to recite "by using a single pair of primers consisting of one primer which is specific for..."

H) Claims 1-15 are indefinite over the recitation of "corresponding to gene liable to be involved" because it is not clear as to what is intended by the "gene liable to be involved". Applicant should clarify whether or not the gene is or is not involved, and furthermore, the claims be point out exact the function of the gene (i.e. target gene for rearrangement, or a sequence of a known gene rearrangement, etc.).

I) Claims 1-15 are indefinite over the recitation of "nucleotidic" because there is no art recognized term for this recitation and it is not defined in the specification. Applicant can amend the claims to recite "nucleotide".

J) Claims 1-15 are indefinite over the recitation of "fusion gene" because it is not clear as to what is meant by a fusion gene. Furthermore, there is no art recognized term for fusion gene, and it is not described in the specification.

K) Claims 1-15 are indefinite over the recitation of "the PCR products" because this recitation lacks antecedent basis. (i.e. there is no recitation of obtaining PCR products).

L) Claims 1-15 are indefinite over the recitation of "carried out by a means of markers" because it is not clear as what a means of markers encompasses. Furthermore, it is not clear as to what markers are.

M) Claims 1-15 are indefinite over the recitation of "specific of gene rearrangements" because it is not clear as to what "gene rearrangements" the markers are specific for.

N) Claims 1-15 are indefinite over the recitation of "a rearrangement" because it is not clear as to what rearrangement is intended (i.e. a single specific rearrangement or a group of rearrangements, etc.).

O) Claims 1-15 are indefinite over the recitation of "in order to detect..." because it is not clear as to how one can only detect genes in "a rearrangement" (which can be interpreted to mean a single specific rearrangement) when the means of detection (i.e. markers which are specific of gene rearrangements, which can be interpreted as many gene rearrangements) are used. In other words it is not clear as to how one can detect only the genes of "a rearrangement" with markers that are specific for all gene rearrangements.

P) Claims 1-15 are indefinite over the recitation of "in their whole" because it is not clear as to who or what "their whole" is refers to. (i.e. does this mean the PCR products as a whole, the genes as a whole, etc.).

Q) Claims 2-10, 13-15 is indefinite over the recitation of "characterized" because this recitation does conform with current U.S. practice. Applicant should amend the claim to recite "comprising". (i.e. The method of claim 1, further comprising...).

R) Claim 2 is indefinite over the recitation of "the amplification step" because this recitation lacks antecedent basis. Applicant could amend the claims to include an amplification step in claim 1. For example, "(a) amplifying the DNA or cDNA by asymmetrical PCR...".

S) Claim 2 is indefinite over the recitation of "include 25 to 40 nucleotides" because it is not clear as to whether or not this recitation should be interpreted as "open" or "closed" claim

language. The claim could be amended to recite "wherein the primers consist of 25 to 40 nucleotides".

T) Claims 2 and 6 are indefinite over the recitation of "Tm is of 75 to 85^0C" because it is not clear as to how primers can have a "Tm is of 75 to 85^0C".

U) Claims 3-4 are indefinite over the recitation of "PCR products are marked in view of the detection step" because it is not clear as to what is meant by this recitation. (i.e. it is not clear as to how one marks PCR products in view of the detection step).

V) Claims 3-5 are indefinite and vague because the claims are written in the passive tense. Method claims should recite positive, active process steps (see Ex parte Erlich 3 USPQ 2d 1011). This rejection may be overcome by amending the claims to recite the active tense, e.g. "(a) denaturing the PCR products; and (b) contacting the denatured PCR products with ...".

W) Claims 3-5 and 9 are indefinite over the recitation of "marked" because it is not clear as to what is meant by "marked". Applicant could amend the claims to recite "lableled".

X) Claims 3-4 are indefinite over the recitation of "specific of..." because it is not clear as to how a nucleotide sequence is specific of the nucleotide sequence of the fusion partners.

Y) Claims 3-4 and 9 are indefinite over the recitation of "fusion partners" because it is not clear as to what is meant by a fusion partner. Furthermore, there is no art recognized term for fusion partners, and it is not clearly described in the specification.

Z) Claim 4 is indefinite over the recitation of "the probes" because this recitation lacks antecedent basis.

AA) Claims 4 and 7 are indefinite over the recitation of "covalently secured" because it is not clear as to what is meant by this recitation, as "covalently secured" is not an art recognized

term. Applicant could amend the claim to recite "covalently bonded". With respect to claim 7, applicant could amend the claim to recite "probes bonded".

AB) Claim 5 is indefinite over the recitation of "probes marked in solution" because it is not clear as to how the probes are marked in solution or what the probes are marked with.

AC) Claim 6 is indefinite over the recitation of "T patterns" because it is not clear as to what is meant by "T patterns". Furthermore, there is no art recognized term for "T patterns" and it is not defined in the specification.

AD) Claims 6 and 8 are indefinite over the recitation of "random repeat of nucleotide pattern" because it is not clear as to what is meant by this recitation. (i.e. it is not clear as to what a nucleotide pattern is and what a nucleotide pattern of random repeats would consist of).

AE) Claim 7 is indefinite over the recitation of "genome DNA or RNA extracted from the sample cells under investigation" because this recitation lacks antecedent basis, as there is no method step encompassing extracting genomic DNA or RNA from a sample of cells under investigation.

AF) Claims 7-8 are indefinite over the recitation of "the sample under investigation" because it is not clear as to what is meant by this recitation.

AG) Claim 7 is indefinite over the recitation of "the PCR steps" because this recitation lacks antecedent basis.

AH) Claims 7 and 9-10 are indefinite over the recitation of "allowed to react" because it is not clear as to whether or not the PCR products react. The recitation "allowed to react" does not constitute a definite method step. With respect to claim 9, "allow hybridization" is indefinite for the same reason.

AI) Claim 7 is indefinite over the recitation of "next, using probes..." because it is not clear as to how "using probes..." can result in the detection of the probes. In addition, it is not clear as to what partner genes are, as this recitation is not defined in the specification.

AJ) Claim 7 is indefinite over the recitation of "the first case" and "the second case" because these recitations lack antecedent basis.

AK) Claim 7 is indefinite over the recitation of "evidencing a rearrangement" because it is not clear as to what "evidencing a rearrangement" means, and furthermore, it is not clear as to how a positive detection of the upstream probe and a negative detection of the downstream probe is evidence of a rearrangement.

AL) Claim 7 is indefinite over the recitation of "the relevant gene" because these recitations lack antecedent basis.

AM) Claim 7 is indefinite because it is not clear as to how a negative detection in the second case is evidence that there is no known fusion product was detected.

AN) Claim 7 is indefinite over the recitation of "the probe PCR products, specific hybridization..." because this confusing and fails to conform with proper English grammar.

AO) Claims 8 and 9 are indefinite over the recitation of "include(s)" because it is not clear as to whether or not this recitation should be interpreted as "open" or "closed" claim language. The claim could be amended to recite "the method of claim 1, wherein the gene rearrangement are translocations associated with the MLL gene, further comprising...".

AP) Claim 8 is indefinite over the recitation of "complemented by a sequence of 6 or 9 random nucleotide patterns" because it is not clear as to what is meant by this recitation.

AQ) Claim 8 is indefinite over the recitation of "the first one" because it is not clear as to what "the first one" refers to.

AR) Claim 8 is indefinite over the recitation of "the oligonucleotide cassette" because this recitation lacks antecedent basis.

AS) Claim 9 is indefinite over the recitation of "fusion transcripts" because it is not clear as to what is meant by this recitation, and it is not defined in the specification.

AT) Claim 9 is indefinite over the recitation of "digoxygenine" because it is not clear as to what is meant by this recitation.

AU) Claim 9 is indefinite over the recitation of "its substrate" because this recitation lacks antecedent basis.

AV) Claim 9 is indefinite over the recitation of "a colored product..." because it is not clear as to whether the colored product reacts with its substrate or the enzyme reacts with its substrate to form a colored product or some other reaction mechanism.

AW) Claim 9 is indefinite over the recitation of "should be bonded" because it is not clear as to what is meant by this recitation.

AX) Claim 9 is indefinite over the recitation of "the enzyme substrate" because this enzyme lacks antecedent basis.

AY) Claim 10 is indefinite over the recitation of "the amplification products" because this recitation lacks antecedent basis.

AZ) Claim 10 is indefinite over the recitation of "partner probes" because it is not clear as to what is meant by this recitation, and furthermore, it is not defined in the specification.

AAA) Claims 11-12 provide for the use of the method in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

AAB)Claim 12 is indefinite over the recitation of "such as" because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

AAC) Claims 13-15 is indefinite over the recitation of "necessary reagents to perform the PCR and detection test" because it is not clear as to what reagents are encompassed by "necessary reagents". Furthermore, it is not clear as to what "suitable solvents or buffers" should be included. Applicant must clearly set forth the contents of the kits.

AAD) Regarding claim 15, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corral et al. (PNAS (1993) 90: 8538-42), in view of Liu et al. (Genomics (1995) 25: 674-681).

Corral teaches acute leukemias of different linkages having similar MLL gene fusions encoding related chimeric proteins resulting from chromosomal translocations. Specifically, the

reference teaches the MLL gene undergoes chromosomal translocation in acute leukemia resulting in gene fusion with AF4 and ENL (see abstract). Furthermore, the reference teaches that the breakpoints of these translocations create this fusion of the MLL gene and the AF4 gene (pg. 8538). The reference also teaches the use of a primer EX5NP (exon 5) in a reverse-anchored-PCR reaction (pg. 8539). The reference further teaches the use of probes in the detection of rearrangements (pg. 8539). The reference does not teach a pair of primers, wherein one primer is a sequence-specific primer and the other primer is a random primer.

Liu teaches the method of thermal asymmetric interlaced PCR. Specifically, Liu teaches the method of asymmetric PCR using a single pair of primers, wherein one primer is a sequence-specific primer and the other primer is a random primer (see abstract). The reference also teaches the detection of the PCR products (pg. 675) and the use of specific probes in genome mapping and map-based cloning programs (pg. 674). Furthermore, the reference teaches that this method is beneficial over other methods for several reasons (i.e. higher specificity, higher efficiency, speed, etc.) (pgs. 679-680).

One of ordinary skill in the art would have been motivated to use the method of Corral to detect gene rearrangements using an anchored PCR method comprising a pair of primers, wherein one primer is a sequence-specific primer, and the other primer is a random primer, to provide a more specific and efficient method of detection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Corral of detecting gene rearrangements associated with the MLL gene, by using a pair of primers, wherein one primer is a sequence-specific primer and the other primer is a random primer, to provide a more effective method of detection. Furthermore, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the methods of Corral and Liu, by using molecular biology assays that are well known and of common knowledge in the art, such as, using a label for detection purposes, antibody-enzyme detection, and the use of solid supports.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
January 9, 2001

KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP ~~1800~~ 1600 1/9/01
Kenneth R. Horlick, Ph.D.

Notice to Comply	Application No.	Applicant(s)	
	09/530,363	GABERT, JEAN	
	Examiner	Art Unit	
	Alexander H. Spiegler	1656	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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